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(54) Title: CENTERFILL DELIVERY SYSTEM FOR NUTRACEUTICALS

(57) Abstract

The present invention relates to a delivery system to control the dosing of nutraceuticals using centerfill confectionery and chewing gum technology. The centerfill has a shell which is a hard confectionery or a chewing gum and a soft core. The shell and the core may each have one or more nutraceuticals. The nutraceuticals are released from the shell by slow dissolution of the hard confection or by mastication of the chewing gum in the oral cavity, and are released from the core by rapid dissolution of core after the shell has been penetrated. The nutraceutical is a botanical, a mineral, a mineral salt or a mixture thereof. Preferably the shell contains one or more mineral or mineral salts, and the core contains one or more botanicals.

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# CENTERFILL DELIVERY SYSTEM FOR NUTRACEUTICALS

## BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to a delivery system for nutraceuticals. In particular, the present invention uses centerfill confectionery and chewing gum technology which includes a shell encasing a soft core to deliver nutraceuticals. The centerfill confectionery or chewing gum may have one or more nutraceuticals in the shell and one or more nutraceuticals in the core.

A nutraceutical is a food or a part of a food which can and should be consumed as part of the daily diet, and which serves to regulate or otherwise affect a particular body process when ingested. Nutraceuticals have also been defined as any substance that may be considered a food or part of a food and provides medical or health benefits, including prevention and treatment of disease. Nutraceuticals can range from isolated nutrients, dietary supplements, and herbal products, to genetically engineered designer foods, as well as processed products.

There is believed that the ingestion of certain food elements is related to health - such as, for example, the link between ingesting calcium and osteoporosis. More strongly, it is thought that ingestion of other substances can have benefits in the prevention and treatment of other diseases. It is also believed that ingestion of certain food elements can have a deleterious effect, such as the link between excess sodium and high blood pressure. Furthermore, the dosage is believed important in terms of (i) the amount of a food element's ingestion and (ii) the speed of its ingestion.

However, certain nutraceuticals have poor taste or poor consistencies that cause them to be difficult to swallow. Further, certain nutraceuticals interact poorly with each other. Certain nutraceuticals can have advantageous effects at a low level with each other but have disadvantageous effects at higher levels. Some nutraceuticals gain benefits from a quick release in the digestive tract, while others gain better benefits from a slow release in the oral cavity. Accordingly, the present invention allows better control of the dosing of nutraceuticals by employing centerfill confectionery and chewing gum technology to deliver the nutraceuticals.

Nutraceuticals include, inter alia, botanicals and minerals. As described above, certain nutraceuticals such as minerals, particularly zinc, are beneficial when released topically in the mouth and less effective when released systemically in the gut. Other nutraceuticals such as botanicals, particularly Echinacea, are the opposite - that is, they are beneficial when released systemically in the gut and less effective when released topically in the mouth. The prior art does not provide for an easy self-contained dosing product which releases a topical nutraceutical in the mouth while also quickly releasing a dose of a botanical systemically to the gut.

Further, there is often a taste incompatibility between two nutraceuticals. It is therefore advantageous to release one nutraceutical quickly while the other taste incompatible nutraceutical is released slower in order to minimize the time that the two incompatible tastes overlap.

The prior art describes how to make confections. U.S. Patent No. 5,578,336 describes a confection having a soft candy center containing from 5% to 40% water by weight. An outer coating contains a vitamin, enzyme, phytochemical, or alimentary vegetable composition. An intermediate coating between the outer coating and the soft candy center prevents moisture in the soft candy center from migrating to degrade the composition of the outer coating. U.S. Patent No.

4,517,205 describes a codeposited two-component hard candy having a hard candy shell encasing a core. The core can be a viscous or a liquid material.

U.S. Patent No. 4,857,331 describes a sugarless pectin delivery system which includes a pectin gel component, an algin gel component, and a polymer network gel component. Edible insoluble solids are entrapped in the gel confectionery unit. Such edible insoluble solids can be a drug or medication. U.S. Patent No. 5,248,503 describes a food product, preferably a liquid, containing in solution two or more ingredients selected from mullen leaf, witch hazel, baptisia (wild indigo), marshmallow root (Althea officianales), Potentilla tormentilla, myrrh, agrimony, blonde root (sanguinaria), bistort, echinacea, parsley, eucalyptus, wintergreen, rosemary, ginger, sandalwood, sweet almond, sassafrass, linseed oil, and castor oil.

U.S. Patent No. 4,260,596 describes an edible unit dosage form comprising an outer shell made of substantially mannitol around a liquid or gel center which may contain a therapeutically effective amount of a medication. U.S. Patent No. 4,929,446 describes a unit dosage form comprising a hard outer shell surrounding a liquid or semi-solid center. The outer shell is essentially composed of sugar while the liquid or semi-solid center includes a medication along with optional sugar syrup for flavor. U.S. Patent No. 4,344,972 describes a herbal center drop comprising a hard bon-bon coat surrounding a core of viscous filling material. The center core filling the material contains the herbal ingredient. The hard bon-bon coat may include ethereal oils and aromatic substances.

U.S. Patent No. 4,762,719 describes a cough drop having enhanced active ingredient activity in the mouth comprising a hard candy outer shell and a powdered center fill. The center fill contains rapidly dissolving powders such as dextrose monohydrate which, when released into the mouth, enhance the active ingredient release to provide aromatic vaporization of the active ingredients such as menthol and eucalyptus. U.S. Patent No. 4,882,153 describes a chewable confectionery delivery system for antitussives comprising precoating the active

ingredient and mixing the precoated active ingredient into a chewable binder system. The described confectionery is chewed and swallowed.

U.S. Patent Nos. 4,684,528 and 4,758,439 describe zinc supplements for oral use comprising a candy base material and a zinc compound together with an amino acid. U.S. Patent No. 4,956,385 describes a method to reduce the duration of common colds by the use of pharmaceutically acceptable zinc compounds applied topically to the oral mucosa by various means. U.S. Patent No. RE. 33,465 describes a method to reduce the duration of common colds through the use of zinc gluconate topically to the oral mucosa. U.S. Patent No. 5,002,970 describes an oral composition containing ionizable compounds of zinc flavor-masked with various taste ingredients for the oral application to the oral mucosa. U.S. Patent No. 5,095,035 describes a composition containing zinc acetate with a sweet, consumable pharmaceutically acceptable carrier for delivery of the zinc to the oral mucosa. U.S. Patent No. 5,286,748 describes a composition for use within the oral cavity that shortens the duration of common colds through the oral and oral pharyngeal absorption of an anti-rhinoviral medication dispersed in a sweet pharmaceutically accepted carrier. U.S. Patent No. 5,409,905 describes a composition for the sustained release of zinc ions within the oral cavity comprising a highly ionizable zinc compound in combination with a pharmaceutically acceptable carrier which masks the taste of zinc. U.S. Patent No. 5,059,416 describes a delivery system for zinc compounds which coats a zinc core material with a hydrophilic coating and forming a second coating which is hydrophobic on top of the hydrophilic coating.

U.S. Patent No. 4,428,927 describes a chewable, filled, one-piece seamless soft elastic gelatin capsule. The capsule includes a shell formed from a formulation of gelatin, water, a plasticizer, and a masticatory substance. U.S. Patent No. 5,595,757 describes a seamless capsule comprising a shell material encapsulating a center-filled core material. The shell material is formed from a carbohydrate in a glassy state.

U.S. Patent 4,139,589 describes a multi-zone pharmaceutical tablet having a non-plastic tablet mass and a chewing gum mass. A pharmaceutically active ingredient can be included in the chewing gum mass or the non-plastic tablet mass. U.S. Patent No. 4,399,154 describes a co-extruded chewing gum having an extruded center portion surrounded by and bonded to an extruded outer shell. Each portion consists of a chewing gum material. U.S. Patent No. 4,450,179 describes a two component soft candy composition which can be produced by coextrusion. U.S. Patent No. 4,684,523 describes a coated edible product comprising a core covered with a shell formed by spraying a sorbitol-aqueous based aqueous syrup on the core.

U.S. Patent Nos. 5,382,424, and U.S. Patent No. 5,300,305 describe an oral composition in the form of microcapsules.

U.S. Patent No. 5,569,477 describes a chewing gum containing vitamins or other active materials released as the gum is masticated. The coated chewing gum includes a gum center containing a water-insoluble gum base and an active material. A shell coating the gum center contains another active material.

French Patent Publication FR 2 608 156 A1 describes a chewing gum tablet containing nicotine for the slow release of nicotine as the chewing gum is masticated. European Patent Application No. EP 0 458 751 A1 describes a delivery system for cyclic amino acid compounds by coating the cyclic amino acid core material with two coatings. The first coating is a polymeric coating and a second hydrophilic coating is placed over the polymeric coating.

U.S. Patent No. 4,316,915 describes a center-filled chewing gum in which the enclosed cavity contains a liquid filling containing a dispersion of a thickener in glycerin. U.S. Patent No. 4,601,907 describes a chewy confection having an outer casing of chewing gum and a center filling also having a chewy consistency. U.S. Patent No 4,466,983 describes a substantially non-aqueous semi-liquid center-fill for use in a chewing gum, confectionery or medication. U.S. Patent No. 4,614,658

describes a filled sugar candy having a hard sugar candy shell encasing a center filling made of a viscous liquid sugar syrup.

International Patent Publication No. WO 95/02967 describes a viscous liquid xylitol composition. International Patent Publication No. WO 97/04662 describes encapsulated aspartic acid sweeteners encapsulated with an encapsulating agent for use in coating syrups to coat pellet chewing gums. International Patent Publication No. WO 93/11754 describes microcapsules of cetylpyridinium chloride and domiphen bromide which reduces oral bacteria and provides breath protection. European Patent Application Serial No. EP 0477 135 A1 describes chewable spheroidal coated microcapsules under about 850 microns in diameter.

United Kingdom Patent Application No. 2 181 646 A describes a medicated chewing gum having a soluble outer coat over a chewable inner core. Both the coat and the core contains pharmaceutically active ingredients. United Kingdom Patent Application No. GB 2 230 439 A describes a nicotine lozenge having a lozenge core and a shell around the lozenge core. Australian Patent Publication No. AU 8930-042-A describes a chewing gum having a soluble outer coat and a chewable inner core where each of the coat and the core includes a pharmaceutically active ingredient. United Kingdom Patent Publication No. GB 2181-646 A describes a chewing gum composition having a soluble outer coat and a chewable inner core, both containing a pharmaceutically active ingredient. U.S. Patent No. 4,867,989 describes a chewing gum mineral supplement having a chewing gum composition coated with an outer shell containing layers of a mineral compound and a coating syrup. International Patent Publication No. WO 86/00226 describes a coated, edible product having a core covered with a shell in which at least the shell has a sorbitol base.

Each of the above patents, patent applications and patent publications is incorporated herein by reference in its entirety.

The control of dosing of nutraceuticals by using centerfill confectionery or chewing gum technology is inadequate as disclosed in the prior art. For example: (i) an ingredient which advantageously should be quickly released into the gut for treatment systemically, is instead released slowly from a gum matrix or a hard candy matrix; and, (ii) an ingredient which advantageously should be released slowly into the oral cavity is instead swallowed into the gut.

## SUMMARY OF THE INVENTION

The present invention concerns centerfill confections and chewing gums for use within the oral cavity to control the dosing of nutraceuticals. The centerfill comprises a hard confectionery or a chewing gum outer shell and a soft core contained within the shell. The shell contains a functionally effective amount of one or more nutraceuticals wherein the nutraceuticals are released by slow dissolution of the shell or mastication of the shell in the oral cavity. The core further contains a functionally effective amount of one or more nutraceuticals wherein the nutraceuticals are released by rapid dissolution of the core in the oral cavity then swallowed. The nutraceutical may be a botanical, a mineral, a mineral salt or a mixture thereof. In one embodiment, the shell contains one or more minerals or mineral salts, and the core contains one or more botanicals. In a further embodiment, the shell further comprises a botanical in a taste effective amount.

The invention further concerns methods to orally deliver nutraceuticals by forming a centerfill confection or chewing gum as described and keeping the centerfill confection or chewing gum in the oral cavity for a substantial period of time.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention provides centerfill confections and chewing gums incorporating nutraceuticals. The present invention further provides for centerfill

confections having a hard confectionery outer shell and a soft core, wherein one or more nutraceuticals can be incorporated into both the shell and the core. The present invention further provides for chewing gums having a chewing gum shell and a soft core wherein one or more nutraceuticals can be incorporated into both the shell and the core.

Wherein more than one nutraceutical is to be delivered the nutraceuticals may be compatible or may be incompatible. The incompatibility may arise from physical or chemical incompatibilities. The incompatibility can also arise from one nutraceutical having a taste which conflicts with the taste of another nutraceutical. The incompatibility can also arise in a combination of nutraceuticals where one nutraceutical is more effective when delivered topically to the tissues of the oral cavity while the other nutraceutical is more effective when delivered systemically to the gut. The tissues of the oral cavity include the mucosal tissues of the nasal and sinus cavities normally in communication with the oral cavity. The gut is that portion of the alimentary canal past the oral cavity.

The present invention utilizes the differences in the physical characteristics of the soft core and the physical characteristics of the shell to allow ingestion of two nutraceuticals that are incompatible. One nutraceutical may be incorporated into the core and the other nutraceutical may be incorporated into the shell.

The present invention takes advantage of the different characteristics pertaining to the rates of release of ingredients from a hard confection shell or a chewing gum shell, and from a soft core. An ingredient incorporated in a hard confection shell is released slowly, as the shell dissolves in the mouth. Similarly, an ingredient incorporated in a chewing gum shell is also released slowly, as the chewing gum shell is masticated in the mouth. By contrast, an ingredient in a soft core is released reatively quickly when the shell encasing the core is broken. The quickly released ingredient from the core is rapidly swallowed into the gut in a very short time relative to ingredients released from a hard confectionery shell or from a

chewing gum shell. Furthermore, the core ingredient stays in the mouth for a much shorter time period than the shell ingredient.

Therefore, with respect to taste, the time interval of bad taste caused by the overlap in the mouth of high amounts of a shell ingredient with the core ingredient is short. The time interval that two nutraceuticals interact at higher concentrations with the taste organs is relatively short thereby minimizing undesirable taste interactions.

The present invention provides for incorporating a nutraceutical in the core that advantageously is delivered rapidly to the gut (systemically) while the nutraceutical incorporated in the shell is advantageously delivered slowly to the oral cavity (topically). In other words, the nutraceutical in the core is one that is more effective when delivered to the alimentary canal past the mouth, while the nutraceutical in the shell is one that is more effective when delivered to the tissues of the oral cavity.

The centerfill confection of the present invention should be kept in the mouth for a period of time, not swallowed immediately. The period of time should be sufficient such that the nutraceutical in the shell is slowly released by the dissolution of a substantial portion of the shell in the mouth. The centerfill chewing gum of the present invention should similarly be kept in the mouth for a period of time sufficient such that the nutraceutical in the shell is slowly released by mastication of the shell in the mouth. In either instance the soft core will be rapidly released when the shell is penetrated. For a hard confectionery shell it is anticipated that this release would occur with rapid dissolution after slow dissolution of a substantial portion of the shell. For a chewing gum it is anticipated that this release would occur with rapid dissolution upon initial mastication of the gum.

Nutraceuticals contemplated for use in the present invention include botanicals, minerals and mineral salts. By "mineral" is meant inorganic substances, metals and the like used in the human diet. Minerals include, but are not limited to,

zinc, calcium, iron and selenium. "Mineral salts" is meant to include the organic and inorganic salts of these minerals and include but are not imited to the gluconate, acetate, chloride and sulfate. A preferred mineral is zinc.

By "botanical" is meant a substance derived from plant source, that is, from roots, leaves, bark or berries of plants, and used in the human diet. These botanicals include, but are not limited to, Echinacea, Siberian Ginseng, Panax Ginseng, Guarana, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra. Other examples include B-sitosterol from wheat germ or corn oil, cafestol from green tea, D-limonene from citrus fruits, kabweol from green tea, nomilin from citrus fruits, oltipraz from cruciferous vegetables, sulphoraphane from broccoli, and tangeretin from tangerines. Further examples include extracts from black tea, folic acid, garlic oil, fiber, green tea extract, lemon oil, mace, licorice, menthol, onion oil, orange oil, rosemary extract, and milk thistle extract. Preferred botanicals are Echinacea and Ginseng.

Certain botanical compounds such as caffeine and licorice are believed better utilized when applied topically. Accordingly, the shell of the present invention can include botanicals such as caffeine and licorice.

The nutraceutical will be present in the centerfill confectionery product or chewing gum in an amount effective to perform the function for which it is intended. The amount of functional ingredient used in the present invention may vary depending upon recommendations derived from the available scientific literature, and/or the recommended or permitted dosage for the particular agent in accordance with the guidelines of, for example, the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Health and Education Act of 1994, and the Food and Drug regulations implementing the Acts. For purposes of the present invention the confectionery shell may contain up to about 5% total nutraceutical by weight of the shell, preferably up to 3%. The chewing gum shell may contain up to about 15% total nutraceutical by weight of the shell, preferably

up to 10%. The core may contain up to about 50% total nutraceutical by weight of the core, preferably up to 40%.

According to an embodiment of the present invention, a mineral is incorporated in an outer hard confectionery shell and a botanical is incorporated in the core encased by the outer hard shell. Advantageously, flavoring ingredients can be included in the core and/or the outer hard shell.

According to another embodiment of the present invention, a mineral is incorporated in an outer chewing gum shell and a botanical is incorporated in the core encased by the outer gum shell. Advantageously, flavoring ingredients can be included in the core and/or the outer gum shell.

The centerfill confections and chewing gums of the present invention can be made by any convenient method well known to one of ordinary skill in the art of making confections and chewing gums. For centerfill hard confectionery products such manufacturing methods include:

(i) Double Deposition, wherein sequential layers are deposited into a mold or onto a substrate;

(ii) Pipe Filling, wherein the outer layer is formed around the exterior of a pipe in which the inner layer is emerging. The outer layer is pulled off the pipe exterior and crimped by a die to form a centerfill confection; and

(iii) Dual Extrusion, wherein the inner and outer layers are coextruded from an extrusion nozzle and nipped off with a rotary die.

Centerfill chewing gums may also be made by Dual Extrusion as described above.

Any hard confectionery formulation may be used for the outer shell of the centerfill confection. Non-grained confectionery products are preferred. Non-

grained confectionery products contain ingredients which prevents migration of sucrose molecules and nucleation. These ingredients, or inhibitors, also known as doctoring agents, slow recrystallation. Examples of such ingredients are invert sugars, cream of tartar, and glucose syrup.

Non-grained hard confectionery formulations include hard boiled candy confections. A highboiled candy is considered non-grained because it is a high viscous glass having low moisture. Hard boiled candy confections generally have a base composed of a mixture of sugar and other carbohydrate bulking agents kept in an amorphous or glassy condition, preferably having from about 0.5% to about 5% moisture. The base normally contains up to about 75% sugar (sucrose) and up to 65% corn syrup (glucose), with a higher sugar to corn syrup ratio. Further ingredients such as flavoring agents, sweetening agents, acidulants, colorants and so forth may also be added. Hard boiled candies may also be prepared from non-fermentable sugars such as sorbitol, mannitol, xylitol, maltitol, isomalt, erythritol, hydrogenated starch hydrolysates and the like.

Such confectionery may be routinely prepared by conventional methods such as those involving fire cookers, vacuum cookers, and scraped-surface cookers also referred to as high speed atmospheric cookers. Once the candy mass has been properly tempered, it may be used in the above described manufacturing processes. A general discussion of the composition and preparation of hard confections may be found in E. B. Jackson, Ed. "Sugar Confectionery Manufacture", 2nd edition, Blackie Academic & Professional Press, Glasgow UK, (1990), at pages 129-169.

The chewing gum shell of the present invention can be any convenient formulation. The gum formulation can be sugar free or it can contain sugar. It generally comprises one or more natural or synthetic elastomers which is supplemented by conventional chewing gum ingredients. These ingredients include one or more solvents, plasticizers, fillers, flavoring agents, coloring agents and/or sweetening agents. A general discussion of chewing gum formulation and

manufacture may be found in Douglas Fritz, "Chewing Gum Formulation", The Manufacturing Confectioner, Sept, 1988, p128-135, and in E. B. Jackson, Ed. "Sugar Confectionery Manufacture", 2nd edition, Blackie Academic & Professional Press, Glasgow UK, (1990), at pages 259-286.

Elastomers which are suitable for use herein include substances of vegetable origin such as chicle, jelutong, gutta percha, guayale and crown gum. Synthetic elastomers such as butadiene-styrene copolymers, isobutylene-isoprene copolymers, polyethylene, polyisobutylene, polyvinylacetate, and mixtures thereof are also useful. The elastomer generally comprises from about 14% to 50% by weight, preferably from about 20% to about 30% by weight, of the chewing gum composition. Polyvinyl acetates may also be used with the elastomers to provide stretch or elasticity to the gum.

The chewing gum composition can contain elastomer solvents to aid in softening the polymer component. Such elastomer solvents can include methyl, glycerol or pentaerythritol esters of rosins or modified rosins, such as hydrogenated, dimerized or polymerized rosins or mixtures thereof. Terpene resins, including polyterpene and mixtures thereof are also useful. The solvent can be employed in an amount ranging from about 10% to 75% and preferably about 15% to about 50% by weight of the chewing gum composition.

A variety of traditional ingredients used as plasticizers or emulsifiers such as lanolin, lecithin, glycerol monostearate, stearic acid, sodium stearate, potassium stearate, glycerol triacetate, triacetin, glycerine and the like can also be incorporated into the chewing gum composition to obtain a variety of textures and consistency properties. These additional materials also include waxes such as natural waxes, petroleum waxes and microcrystalline waxes and fats and oils including animal fats such as lard and tallow, vegetable oils such as soybean and cottonseed oil, hydrogenated and partially hydrogenated vegetable oil and cocoa butter. These ingredients are generally employed in amounts of up to about 30 %

by weight, preferably 1% to 25% by weight and more preferably from about 3% to about 7% by weight of the final chewing gum composition.

The chewing gum composition can additionally include conventional coloring agents such as titanium dioxide, in amounts up to 2% and fillers such as dicalcium phosphate, magnesium carbonate, aluminum hydroxide, alumina, aluminum silicates, talc, calcium carbonate, cellulose, and combinations thereof in amounts of from 5 to 35 % by weight of the final composition.

The chewing gum composition may also contain bulk sweeteners including sugars such as sucrose, dextrose, maltose, fructose and the like or sugar alcohols such as sorbitol, mannitol, xylitol, maltitol, isomalt, erythritol and hydrogenated starch hydrolysates and combinations thereof. Bulk sweeteners may be present in amounts up to 90% by weight of the final composition. High intensity sweeteners such as aspartame, acesulfame salts, aliatame saccharin and the like may also be present. These sweeteners may be present in amounts of up to 1% by weight of the final gum composition.

The chewing gum may contain flavoring agents in addition to the enhanced flavoring compositions in amounts up to 3.5%. Generally any food additive such as those described in "Chemicals Used In Food Processing", publication 1274, pages 63-258, by the National Academy of Sciences, may be used.

The chewing gum is generally manufactured by methods known in the art by sequentially adding the various chewing gum components to any commercial mixer or extruder in a batch or continuous process. After the ingredients have been thoroughly mixed the mass is discharged and fed to centerfill forming equipment.

The soft core of the present invention is an edible material which may be flowable at ambient temperature, e.g., about 20°C, or greater, and is flowable at temperatures of the oral cavity, i.e., about 37°C , or greater. The edible material can be comprised of single or multi-component edible materials such as oils, fats,

starches, sugars, sugar alcohols, hydrogenated sugars, proteins, hydrocolloids, water and the like. The materials are generally mixed, blended or cooked to form the core material. Ingredients used in traditional candy making such as sugar, glucose, flavorants, colorants and the like, as discussed previously herein, are preferred for use in the core for both the centerfill confection and the centerfill chewing gum.

The core will be from about 5% to about 35 % by weight of the total weight of the confection or chewing gum with 7% to 20% being preferred.

The shape of the centerfill confection or chewing gum of the present invention can be any convenient shape and size including, for example, ovoid, rectangular, circular, and square.

The following examples illustrate the preferred embodiments of the invention and are intended to include all variations thereof. Other variations and modifications of this invention will be apparent to those skilled in this art after careful study of this application. This invention is not to be limited except as set forth in the claims.

## EXAMPLES

Example 1: Centerfill Confection

A centerfill boiled candy containing zinc and Echinacea in the shell and Echinacea in the core was made according to the constituents in Table 1 below. The amounts are given in percent by weight.

TABLE 1

| | Example 1* |
|---|---|
| Shell | 90.0 |
| Core | 10.0 |
| | 100.0 |
| Shell | |
| Sugar, fine granulated | 51.74 |
| Glucose syrup | 42.16 |
| Residual Moisture | 1.92 |
| Partially Hydrogenated Cottonseed Oil | 1.51 |
| Color Soln., 6.0% | 0.01 |
| Zinc Gluconate | 0.98 |
| Flavor Blend** | 1.17 |
| Echinacea Purpurea Herb | 0.51 |
| Core | |
| High Fructose Corn Syrup | 50.82 |
| Sugar, Fine Granulated | 2.48 |
| Echinacea Purpurea Herb | 9.29 |
| Residual Moisture | 10.76 |
| Flavor Blend** | 1.73 |
| Glycerine | 24.91 |
| | 100.00 |

*percent by weight

**mentholated cherry flavor composed of characteristic flavors and sweeteners

The shell of Example 1 was prepared by conventional manufacture methods. Concurrently, the core was formed by cooking until the resulting cooked core had approximately 85% solids by weight. The confection was formed by coextruding the shell mixture and the core mixture forming a rope having the core within a tube formed from the shell mixture. The rope was feed into a rotary forming unit to form individual confections having an oval shape.

The zinc gluconate contained 14% elemental zinc and provided 5.0 mgs elemental zinc per 4 gm piece. The Echinacea extract was a liquid extract of E. purpurea, diluted 4:1 by volume. The shell provided 18 mgs and the core provided 38 mgs of Echinacea for a total 56 mgs per 4.0 gm piece. The total weight of each confection piece was 4.0 g.

A study with 450 participants was conducted, comparing the centerfill confection of Table 1 with a solid lozenge having the same amounts of zinc and Echinacea of the Formula in Table 2 below. The lozenge was manufactured by conventional techniques. Consumers found flavor acceptance for the centerfill lozenge to be significantly greater when compared to the solid lozenge flavor. Accordingly, putting about 95% of the Echinacea into the syrup core, and about 5% of the Echinacea with the zinc in the shell wherein it provided a slight stimulating effect which masked the inherent chalkiness of the zinc, resulted in a significantly better tasting shell. Consumers further found the centerfill form itself to be an acceptable delivery system when compared with the lozenge form.

TABLE 2

| | Comparative Lozenge* |
|---|---|
| Sugar, fine granulated | 50.15 |
| Glucose syrup | 40.87 |
| Residual Moisture | 1.84 |
| Partially Hydrogenated Cottonseed Oil | 1.49 |
| Color Soln., 6.0% | 0.01 |
| Zinc Gluconate | 0.93 |
| Flavor Blend** | 1.25 |
| Echinacea Purpurea Herb | 1.47 |
| Salvage | 1.99 |

*percent by weight

**mentholated cherry flavor composed of characteristic flavors and sweeteners

Examples 2 and 3

Example 2 provides a centerfill gum containing zinc in the gum shell and Echinacea in the core. Example 3 provides a centerfill gum containing caffeine (Guarana) in the gum shell and Ginseng in the core. The compositions are provided in Table 3 below. The amounts are given in percent by weight. The gum is made by conventional blending of the ingredients with the gum base. The center in made in a manner similar to Example 1. The finished gum is extruded to form a

rope with the prepared liquid core pumped into the rope center. The rope is sized and formed to a pillow-type gum.

TABLE 3

| | Example 2* | Example 3* |
|---|---|---|
| Shell | 85.0 | 85.0 |
| Core | 15.0 | 15.0 |
| | 100.0 | 100.0 |
| Shell | | |
| Gum Base | 20.0 | 20.0 |
| Sugar | 59.45 | 57.45 |
| Glucose Syrup | 14.0 | 14.45 |
| Monoglycerides | 0.15 | 0.15 |
| Glycerine | 1.00 | 1.00 |
| Flavor | 1.45 | 1.50 |
| Color | 0.01 | 0.01 |
| Zinc Acetate | 1.47 | ------ |
| Caffeine (Guarana) | ------- | 2.94 |
| Moisture | 2.50 | 2.50 |
| | 100.00 | 100.00 |
| Core | | |
| High Fructose Corn Syrup | 59.0 | 68.00 |
| Sugar | 1.50 | 3.49 |
| Glycerine | 1.00 | 1.00 |
| Lecithin | 0.50 | 0.84 |
| Flavor | 1.00 | 1.00 |
| Echinacea extract (4:1) | 28.00 | ---- |
| Ginseng Std. Extract (7%) | ------ | 16.67 |
| Moisture | 9.00 | 9.00 |
| | 100.00 | 100.00 |

*percent by weight

Examples 4 and 5

Example 4 provides a centerfill boiled hard candy containing zinc in the shell and Echinacea in the core. Example 5 provides a centerfill boiled hard candy containing caffeine in the shell and Ginseng in the core. The constituents are provided in Table 4 below. The amounts are given in percent by weight. The candies are made by processes similar to the process described above for Example 1.

TABLE 4

| | Example 4* | Example 5* |
|---|---|---|
| Shell | 90.0 | 90.0 |
| Core | 10.0 | 10.0 |
| | 100.0 | 100.0 |
| Shell | | |
| Sugar | 52.10 | 51.40 |
| Glucose syrup | 42.50 | 41.81 |
| Flavor | 1.50 | 1.50 |
| Color | 0.01 | 0.01 |
| Zinc Acetate | 1.39 | ----- |
| Caffeine (Guarana) | ----- | 2.78 |
| Moisture | 2.50 | 2.50 |
| | 100.00 | 100.00 |
| Core | | |
| High Fructose Corn Syrup | 46.0 | 60.0 |
| Sugar | 1.00 | 3.00 |
| Glycerine | 0.95 | 1.00 |
| Lecithin | 0.05 | 1.00 |
| Flavor | 1.00 | 1.00 |
| Echinacea Extract (4:1) | 42.00 | ---- |
| Ginseng Std. Extract | ------ | 25.00 |
| Moisture | 9.00 | 9.00 |
| | 100.00 | 100.00 |

*percent by weight

What is claimed is:

1. A centerfill confection for use within the oral cavity to control the dosing of nutraceuticals comprising:

a) a hard confectionery outer shell containing a functionally effective amount of one or more nutraceuticals wherein said nutraceuticals are released by slow dissolution of said shell in the oral cavity, and

b) a soft core contained within said shell containing a functionally effective amount of one or more nutraceuticals wherein said nutraceuticals are released by rapid dissolution of said core.

2. The centerfill confection according to claim 1 wherein the core is a material which is flowable at about at least 20°C.

3. The centerfill confection according to claim 2 wherein the core is a material which is flowable at about at least 37°C.

4. The centerfill confection according to claim 1 wherein the core is a liquid or semi-solid.

5. The centerfill confection according to claim 4 wherein the core has a solids range of 10% to 95% by weight of the core.

6. The centerfill confection according to claim 5 wherein the core has a solids range of 75% to 95% by weight of the core.

7. The centerfill confection according to claim 1 wherein the nutraceutical is a botanical, mineral, mineral salt or a mixture thereof.

8. The centerfill confection according to claim 7 wherein the mineral is selected from the group consisting of zinc, calcium, iron and selenium; the mineral salt is selected from the group consisting of inorganic salts of zinc, calcium, iron and

selenium; the botanical is selected from the group consisting of Echinacea, Siberian Ginseng, Panax Ginseng, Guarana, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, B-sitosterol, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphoraphane, tangeretin, black tea, folic acid, garlic oil, fiber, green tea extract, lemon oil, mace, licorice, menthol, onion oil, orange oil, rosemary extract, and milk thistle extract.

9. The centerfill confection according to claim 8, wherein the botanical is Echinacea or Ginseng, the mineral is zinc and the mineral salt is a zinc salt.

10. The centerfill confection according to claim 7, wherein the shell contains one or more minerals or mineral salts, and the core contains one or more botanicals.

11. The centerfill confection according to claim 10, wherein the shell further comprises a botanical.

12. The centerfill confection according to claim 1 wherein the core is from about 5% to about 35% by weight of the total weight of said confection.

13. The centerfill confection according to claim 12 wherein the core is from 7% to 20% by weight of the total weight of said confection.

14. The centerfill confection according to claim 1, wherein the shell contains up to about 5% total nutraceutical by weight of the shell.

15. The centerfill confection according to claim 1, wherein the core contains up to about 50% total nutraceutical by weight of the core.

16. The centerfill confection according to claim 14, wherein the shell contains up to 3% total nutraceutical by weight of the shell.

17 The centerfill confection according to claim 15, wherein the core contains up to 40% total nutraceutical by weight of the core.

18. A centerfill chewing gum for use in the oral cavity to control the dosing of nutraceuticals comprising:

a) a chewing gum outer shell containing a functionally effective amount of one or more nutraceuticals wherein said nutraceuticals are released by mastication of said shell in the oral cavity, and

b) a soft core contained within said shell containing a functionally effective amount of one or more nutraceuticals wherein said nutraceuticals are released by rapid dissolution of said core.

19. The centerfill chewing gum according to claim 18 wherein the core is a material which is flowable at about at least 20°C.

20. The centerfill chewing gum according to claim 19 wherein the core is a material which is flowable at about at least 37°C.

21. The centerfill chewing gum according to claim 18 wherein the core is a liquid or semi-solid.

22. The centerfill chewing gum according to claim 21 wherein the core has a solids range of 10% to 95% by weight of the core.

23. The centerfill chewing gum according to claim 22 wherein the core has a solids range of 75% to 95% by weight of the core.

24. The centerfill chewing gum according to claim 18 wherein the nutraceutical is a botanical, mineral, mineral salt or a mixture thereof.

25. The centerfill chewing gum according to claim 24 wherein the mineral is selected from the group consisting of zinc, calcium, iron and selenium; the mineral

salt is selected from the group consisting of inorganic salts of zinc, calcium, iron and selenium; the botanical is selected from the group consisting of Echinacea, Siberian Ginseng, Panax Ginseng, Guarana, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, B-sitosterol, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphoraphane, tangeretin, black tea, folic acid, garlic oil, fiber, green tea extract, lemon oil, mace, licorice, menthol, onion oil, orange oil, rosemary extract, and milk thistle extract.

26. The centerfill chewing gum according to claim 25, wherein the botanical is Echinacea or Ginseng, the mineral is zinc and the mineral salt is a zinc salt.

27. The centerfill chewing gum according to claim 24, wherein the shell contains one or more minerals or mineral salts, and the core contains one or more botanicals.

28. The centerfill chewing gum according to claim 27, wherein the shell further comprises a botanical.

29. The centerfill chewing gum according to claim 18 wherein the core is from about 5% to about 35% by weight of the total weight of said confection.

30. The centerfill chewing gum according to claim 29 wherein the core is from 7% to 20% by weight of the total weight of said confection.

31. The centerfill chewing gum according to claim 18, wherein the shell contains up to about 15% total nutraceutical by weight of the shell.

32. The centerfill chewing gum according to claim 18, wherein the core contains up to about 50% total nutraceutical by weight of the core.

33. The centerfill chewing gum according to claim 31, wherein the shell contains up to 10% total nutraceutical by weight of the shell.

34. The centerfill chewing gum according to claim 32, wherein the core contains up to 40% total nutraceutical by weight of the core.

35. A method to orally deliver nutraceuticals, said method comprising:

a) forming a centerfill confection, wherein said centerfill confection includes a confectionery outer shell encasing a soft core wherein said shell and said core each contain a functionally effective amount of one or more nutraceuticals, and

b) keeping said centerfill confection in the oral cavity for a substantial period of time.

36. A method to orally deliver nutraceuticals, said method comprising:

a) forming a centerfill chewing gum, wherein said centerfill chewing gum includes an chewing gum outer shell encasing a soft core wherein said shell and said core each contain a functionally effective amount of one or more nutraceuticals, and

b) keeping said centerfill chewing gum in the oral cavity for a substantial period of time.

# INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/US 99/12691

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K9/00 A23G3/00 A23G3/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| X | US 4 762 719 A (FORESTER)<br>9 August 1988 (1988-08-09)<br>cited in the application<br>column 1, line 5 - line 24<br>column 2, line 19 - line 22<br>column 2, line 41 - line 47<br>column 3, line 5 - line 8<br>example 1; table 1<br>claims 1-9<br>---<br>-/-- | 1-4,7,8,<br>12-17,35 |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 7 October 1999 | 19/10/1999 |

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# INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 99/12691

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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